REMARKS

Claims 44-92 are pending in the application. By this Amendment, Claim 44 is amended and Claims 63-92 are added. Favorable reconsideration is respectfully requested in light of the following Remarks.

I. Formal Matters

1. Applicants acknowledge that the drawings and photographs submitted February 4, 2002 fail to comply with 37 CFR 1.84. Acceptable drawings will be submitted upon the indication of allowable subject matter.

2. Applicants acknowledge that the present application is a Continuation Patent Application (CPA) and, thus, no update of the status of the present application is needed because the indication of the status of the present application as a CPA will be duly noted on the face of the issued patent.

3. Applicants acknowledge that the Office action indicates that Claims 48-53 and 57-59 are directed to a non-elected invention with Claim 44 being a generic linking claim, and upon allowance of Claim 44, the restriction requirement will be withdrawn and any claim depending from or otherwise including all the limitations of Claim 44 will be entitled to examination in the instant application.

II. The Claims Define Patentable Subject Matter

1. The Office action rejects Claims 44-46, 54-56, and 60-62 under 35 U.S.C. §103(a) as being unpatentable over Oprandy et al. (Journal of Clinical Microbiology, 1990, see IDS #5, hereinafter "Oprandy"), in view of Huang et al. (U.S. Patent No. 5,712,172, hereinafter "Huang"), and WHO Bulletin (Bulletin of World Health Organization, 1996, see IDS #5, hereinafter "the WHO Bulletin"). The rejection is respectfully traversed.

Independent Claim 44 specifies, *inter alia*, a method for analyzing an arthropod sample for the presence of one or more analytes associated with an arthropod-carried agent that causes a disease in mammals. The method comprises the steps of:

obtaining an arthropod sample suspected of containing arthropod-borne agents;

grinding the sample in solution to expose an analyte associated with the arthropod-carried agent such that the sample contains arthropod debris after grinding;

contacting the sample containing arthropod debris with a liquid permeable support and at least one detectable analyte-specific reagent that binds to the analyte to form an analyte-reagent complex;

allowing the liquid phase to move vertically upward through the support by capillary flow or wicking until the analyte or the analyte-specific reagent or the analyte-specific reagent complex binds to at least one capture reagent immobilized on the support; and

detecting the presence of the detectable analyte-specific reagent indicating the presence of the analyte in the sample.

Applicants agree with the Office action that there is no mention in Oprandy of the step of applying the sample to a dipstick device for the detection of the analyte, as recited in Claim 44. However, in order to overcome this shortcoming in Oprandy, the Office action asserts that it would have been obvious to modify Oprandy with teaching of Huang and the WHO Bulletin to meet the claimed invention. Applicants disagree with this assertion.

Specifically, Applicants assert that there is no motivation to combine Oprandy with Huang and the WHO Bulletin to meet the claimed invention. Oprandy is directed to a dot-blot immunobinding assay to detect arthropod-borne agents. The system involves a two-step process that solubilizes antigen and microfilters debris and immobilizes target molecules onto a single phase. Arthropod vectors are homogenized in sodium dodecyl sulfate (SDS) and then spot filtered with pressure through a two-membrane sandwich. The first membrane is a nonbinding hydrophilic membrane and serves to exclude debris. The second membrane is a high-protein-binding-capacity hydrophobic polyvinylidene difluoride (PVDF). *See Page 1701, first column, second paragraph.*

In addition, Oprandy teaches that the use of brittle nitrocellulose in membrane-based tests is undesirable because of the possibility of high backgrounds. *See Page 1701, first column, first paragraph.* A prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that

was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553, 31 USPQ 2d 1130, 1131 (Fed. Cir. 1994). Thus, Oprandy teaches away from the use of nitrocellulose in membrane-based tests.

Huang is directed to a one step lateral flow immunochromatographic assay device. The device comprises a series of porous material pieces 2, preferably nitrocellulose material, and porous paper material 3, 4 that are laminated to an elongated strip of semi-rigid material 1, such as vinyl. *See col. 5, 12-18; col. 8, lines 4-7; col. 9, lines 43-45; col. 10, lines 43-48.* In Huang, it is critical that the device has adequate mechanical strength for the device to properly function. *See col. 10, lines 11-16.* To this end, Huang teaches that the mechanical strength or rigidity of the device be measured two different ways with the result being that the less the device bends, the more favorable the results. *See Figs. 6a, 6b; col. 9, line 62-col. 10, line 11.* In Huang, the less the device bends, the more favorable the results.

Because Huang teaches the use of nitrocellulose for the porous material to achieve adequate mechanical strength critical for providing favorable test results and Oprandy teaches away from the use of nitrocellulose because of the high backgrounds, one of ordinary skill in the art at the time the invention was made would not be motivated to combine the teachings of Oprandy and Huang to meet the claimed invention.

The WHO Bulletin is directed to a dipstick assay for the detection of a malarial antigen found in the blood of an infected patient. As admitted in the Office action, the WHO Bulletin does not teach the detection of a mosquito stage antigen from a mosquito sample. Thus, one of ordinary skill in the art would not be motivated to combine the teaching of the WHO Bulletin directed to a dipstick assay for the detection of a malarial antigen in a blood sample with the teaching of Oprandy directed to a dot-blot immunobinding assay of a mosquito sample and with the teaching of Huang directed to a lateral flow device for the detection of an analyte in a urine sample.

In view of the foregoing, it is respectfully submitted there is no motivation in the applied references or in the general knowledge of one of ordinary skill in the art at the time the invention was made to combine the teachings of the applied art to meet the claimed invention. Because there is no motivation in the applied references or in the general knowledge of one of ordinary skill in the art at the time the invention was made, the Office Action Even if there is proper motivation to combine Oprandy, Huang and the WHO Bulletin,

the combination of Oprandy, Huang and the WHO Bulletin do not disclose all the claim limitations. As admitted in the Office action, Oprandy does not teach applying the sample to a dipstick device for the detection of arthropod-borne agents. In addition, the Office action admits that Huang does not teach detecting an etiologic agent from a mosquito sample. Further, the Office action admits that the WHO Bulletin does not teach the detection of a mosquito stage antigen from a mosquito sample. Thus, the Office action admits that the applied art does not teach at least the step of contacting the sample containing arthropod debris with a liquid permeable support and at least one detectable analyte-specific reagent that binds to the analyte to form an analyte-reagent complex, as recited in Claim 44. For at least this additional reason, the Office Action fails to establish a *prima facie* case of obviousness.

In view of the foregoing, Claim 44 is allowable over the applied art, taken singly or in combination. Claims 45, 46, 54-56 and 60-62, which depend from Claim 44, are likewise allowable over the applied art, taken singly or in combination. Withdrawal of the rejection is respectfully requested.

2. The Office action rejects Claims 44-47, 54-56, and 60-62 under 35 U.S.C. §103(a) as being unpatentable over Oprandy in view of Huang and the WHO Bulletin, and further in view of Rattenarithikuln et al. (American Journal of Tropical Medicine, 1996, hereinafter "Rattenarithikuln") and Sithiprasasna et al. (Annals of Tropical Medicine and Parasitology, hereinafter "Sithiprasasna"). The rejection is respectfully traversed.

Claim 47 depends from Claim 44. Neither Rattanarithikuln nor Sithiprasasna teach or motivate the selection and use of monoclonal antibodies in the detection of different arthropod-borne disease vectors or pathogens, as recited in Claim 44. Thus, Rattanarithikuln and Sithiprasasna add nothing to overcome the shortcomings of Oprandy, Huang and the WHO Bulletin discussed in Section II.1 above.

In view of the foregoing, Claim 47 is allowable over the applied art, taken singly or in combination. Withdrawal of the rejection is respectfully requested.

New independent Claim 63 recites the step of contacting the sample containing arthropod debris with a dipstick and at least one detectable analyte-specific reagent that binds to the analyte to form an analyte-reagent complex. For at least the same reason stated for Claim 44, Claim 63 is allowable over the applied art, taken singly or in combination. Claims

64-78, which depend from Claim 63, are likewise allowable over the applied art, taken singly or in combination.

New independent Claim 79 specifies, *inter alia*, a method for analyzing an arthropod sample for the presence of one or more analytes associated with an arthropod-carried agent that causes a disease in mammals, said method comprising the step of contacting the sample containing arthropod debris with a panel assay having capture reagents immobilized onto separate areas and detectable analyte-specific reagents specific for an analyte associated with each arthropod-borne agent to which the capture reagents are directed.

It is respectfully submitted that at least this step is not disclosed, taught or suggested in the applied art. For at least this reason, Claim 79 is allowable over the applied art, taken singly or in combination. Claims 80-92, which depend from Claim 79, are likewise allowable over the applied art, taken singly or in combination.

CONCLUSION

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Favorable consideration and prompt allowance of the application is earnestly solicited.

Should Examiner Winkler believe anything further would be desirable in order to place the application in better condition for allowance, the Examiner is invited to contact the undersigned attorney at the telephone number listed below.

It is believed that any additional fees due with respect to this paper have already been identified. However, if any additional fees are required in connection with the filing of this paper, permission is given to charge account number 18-0013 in the name of Rader, Fishman and Grauer PLLC.

Respectfully submitted,

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MARKED UP VERSION OF ALL AMENDED CLAIMS

44. (Twice Amended) A method for analyzing an arthropod sample for the presence of one or more analytes associated with an arthropod-carried agent that causes a disease in mammals, said method comprising the steps of:

~~(a)~~ obtaining an arthropod sample suspected of containing arthropod-borne agents;

~~(b)~~ grinding the sample in solution to expose an analyte associated with the arthropod-carried agent such that the sample contains arthropod debris after grinding;

~~(c)~~ contacting ~~a liquid permeable support with~~ the sample containing arthropod debris ~~from step (b)~~with a liquid permeable support and ~~a~~ at least one detectable analyte-specific reagent that binds to the analyte to form an analyte-reagent complex~~;, wherein said support comprises, in order:~~

~~(i) a sample pad adapted for receipt of the sample;~~

~~(ii) at least one conjugate pad having immobilized thereto a capture reagent that binds to the analyte or the analyte-specific reagent or the analyte-specific reagent complex;~~

~~(iii) an absorbent pad adapted to facilitate vertical liquid flow along the liquid permeable support;~~

~~wherein the liquid permeable support does not include a filter to remove cellular debris or particulate matter;~~

~~(d)~~ allowing the liquid phase to ~~vertically~~ move vertically upward through the support by capillary flow or wicking until the analyte or the analyte-specific reagent or the analyte-specific reagent complex binds to ~~the~~ at least one capture reagent immobilized on the support; and

~~(e)~~ detecting the presence of the detectable analyte-specific reagent indicating the presence of the analyte in the sample.